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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,982	04/03/2002	Evelyne Lopez	15675P398	4095

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,982	LOPEZ ET AL.	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-15,18-23,26-28,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-15,18-23,26-28,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on June 7, 2004. Acknowledgment is made of Applicant's cancellation of Claims 7, 16 and 17 and newly added Claims 31-32.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 8-15, 18-23, 26-28 and 31-32 are under examination.

Claim Rejections - 35 USC § 112

Claims 1-6, 8-15, 18-23, 26-28 as amended and newly added Claims 31-32 remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 1 recites the limitation "the extraction mixture" in line 8. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by adding to obtain an extraction mixture after "solution" in line 6.

Claim 31 recites the limitation "the extraction mixture" in line 8. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by adding to obtain an extraction mixture after "solution" in line 7.

Although not rising the level of uncertainty, the recitation of the phrase "reducing mother-of-pearl to a powder with a particle size of between approximately 1 and

approximately 300 μm" renders the claim language somewhat indefinite. It would appear that Applicant intends to direct the invention to a method of making a composition comprising a process step of reducing mother-of-pearl to a powder to a particle size. Appropriate correction is required, if necessary.

Claim 32 recites the limitation "wherein the aqueous-glycolic solvent " in line1. There is insufficient antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 13-15 and 18 as amended are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Masaki (N,

translation of foreign patent provided herein). Newly applied as necessitated by amendment.

Applicant claims a method for preparing a composition comprising the steps of: a) reducing mother-of-pearl to a powder to a particle size of between approximately 1 and approximately 300 μm; b) bringing the mother-of-pearl powder thus obtained into contact with an extracting agent in the form of an aqueous-glycolic solution; and c) recovering the extraction mixture formed as a result of the bringing into contact with the extracting agent. Applicant further claims a pharmaceutical composition using the method as claimed in claim 1.

Masaki teaches a method of making an extract of mother-of-pearl shellfish using an aqueous-glycolic solution, *e.g.*, 1,3-butylene glycol, propylene glycol, dipropylene glycol and glycerol, as an extracting agent, in [0011] of the translated document. In [0012] of the translated document, Masaki teaches grinding a shellfish fragment prior to extraction. Masaki further teaches pharmaceutical compositions, *e.g.,* lotion, cream and ointment, comprising an effective amount of the reference mother-of-pearl composition, which is applied to the skin to provide a therapeutic method for the treatment of disorders of the skin, such as wrinkling of the skin or reduced elasticity of the skin.

The claims are drawn to a method of preparing a composition comprising reducing mother-of-pearl to a powder to a particle size of between approximately 1 and approximately 300 μm; bringing the mother-of-pearl powder thus obtained into contact with an extracting agent in the form of an aqueous-glycolic solution; and, recovering the

extraction mixture formed as a result of the bringing into contact with the extracting agent; and a pharmaceutical composition obtained thereof.

The teachings of Masaki are set forth above. The cited reference teaches a method for preparing a composition comprising reducing mother-of-pearl to a powder to a reduced particle size; bringing the mother-of-pearl powder into contact with an aqueous-glycolic solution to obtain an extraction mixture; recovering the resultant extraction mixture; and, using the resultant mother-of-pearl extraction mixture to obtain pharmaceutical compositions, which are applied to the skin of a subject in need thereof to provide therapeutic treatments of skin disorders. Thus, the reference method of making a product and the product-by-process thereof appear to be identical to the presently claimed method of preparing a composition and the pharmaceutical composition - - each of the instantly claimed inventions appear to be identical to the presently claimed inventions, since Masaki teaches the same ingredients, essentially the same amounts or ratios of the same ingredients, and the same product-by-process made thereof having the same beneficial functional effect for treating skin disorders when applied to a subject in need thereof, as instantly claimed by Applicant; and the Masaki' reference is therefore, considered to anticipate the claimed method of preparing a composition and a composition thereof.

In the alternative, even if the claimed method of preparing a composition and the claimed composition prepared thereof are identical to the reference method of preparing a mother-of-pearl extract and the reference product-by-process thereof with regard to some unidentified characteristics, the differences between that which is disclosed and

that which is claimed are considered to be so slight that the referenced method of preparing a composition and product-by-process thereof are likely to inherently possess the same characteristics of the claimed inventions particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed inventions would have been obvious to those of ordinary skill in the art within the meaning of USC 103. For instance, it is not clear from the teachings of Masaki the particle size of the mother-of-pearl powder, which is used in the making of the reference composition. However, Masaki does expressly teach a process step of grinding fragments of mother-of-pearl shellfish prior to bringing the mother-of-pearl powder into contact with the extraction agent in the form of an aqueous glycolic solution. Thus, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one of ordinary skill in the art would have been motivated and had a reasonable expectation of success to optimize the method and product-by-process thereof taught by Masaki by adjusting the particle size of the mother-of-pearl powder to the instantly claimed size range because Masaki expressly teaches that processing a fragment of the mother-of-pearl shellfish by homogenization, desiccation and grinding increases extraction efficiency in [0012]; and, in [0020], Masaki expressly teaches the percentage amounts of the mother-of-pearl powder and aqueous-glycolic extracting agent to obtain the reference composition. Thus, the instantly claimed process step for reducing the particle size of the claim-designated ingredient to the instantly claimed size would have been no more than a matter of routine optimization to one of ordinary skill in the art practicing the invention at the time the invention was made since Masaki teaches the

ingredients, the amounts or the ratios of the ingredients; and the process steps for reducing the particle size of mother-of-pearl to obtain a powder to provide a composition having beneficial functional effects for the treatment of skin disorders when incorporated into the making of pharmaceutical compositions.

The United States Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether on not Applicants' method of making a product and a product of process thereof differ and, if so, to what extent, from that discussed in the reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to Applicants.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Allowable Subject Matter

Claims 31 and 32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 5, 6, 8-14, 19-23 and 26-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PATENT EXAMINER

MCF
September 2, 2004